84

APR 9 1985

THE TOXIC SUBSTANCES CONTROL ACT
GOOD LABORATORY PRACTICES REGULATIONS
ENFORCEMENT RESPONSE POLICY

OFFICE OF COMPLIANCE MONITORING
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
U. S. ENVIRONMENTAL PROTECTION AGENCY

Response- When a violation is discovered, the penalty clock commences from the date the violation began to the inspection date. For both notices of non-compliance and civil penalties, violators (lab/sponsor) are expected to take corrective action and cease the violative activity immediately. If 1) the Region suspects that the violative activity has not ceased, 2) the Agency has identified a serious violation, or 3) the Agency plans to conduct another inspection at the same site for any reason, then a reinspection to determine whether past violative activity has ceased is warranted. Since study invalidation can result in severe regulatory corrective action, i.e., repeat the study, it is appropriate that daily penalties be assessed for these situations. Continuing violations are to be assessed in cases where the sponsor/lab was aware of a violation and fails to take corrective action or falsifies data/records. Otherwise, enormous penalties would be assessed for valid studies. The ERP now reflects this additional language to provide clarity.

Comment 6- The Extent Categories appear arbitrary without convincing rationale. If these criteria are retained, the rationale, such as the longer the study the more serious the disruption to EPA because of the increased time to generate acceptable data, should be stated in the policy.

Response- To eliminate the appearance of being arbitrary, a rationale has been incorporated into the ERP. The rationale described above displays a proper understanding of the intent.

Comment 7- A penalty policy should be developed that would rest solely upon the GLP regulations. This could be accomplished by structuring the circumstance criteria in a fashion similar to the way PCB violations are defined in the PCB penalty policy.

Response- We have considered this proposal and have determined that the structure appearing in the final policy is appropriate for the present time. However, as we gain experience, we will consider the feasibility of amending this structure.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR - 9 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Final TSCA GLP Enforcement Response Policy

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the final Enforcement Response Policy (ERP) for the Toxic Substances Control Act (TSCA) Good Laboratory Practice (GLP) Regulations published on November 29, 1983 (48 FR 53922). This regulation, which is also attached, became effective on December 29, 1983.

We appreciate the time and effort spent by the various program offices and Regions in reviewing this document. The January 17, 1985 final draft ERP incorporated changes in the Extent and Circumstances Sections based on previous comments from the Regions. The Circumstances Section has been reduced from six to three levels to eliminate the confusion in determining the degree of impairment in the Agency's ability to evaluate the hazards of chemicals. The Extent Section has been modified to eliminate the overlap that appeared between the Extent and Circumstances Sections in the previous drafts.

OCM received several non-editorial comments on the January 17 draft which are discussed in the attachment. If you have any questions concerning this ERP, please call Richard Green of my staff at (FTS) 382-7845.

Attachments

Addressees

Marcia Williams (TS-788)
Don Clay (TS-792)
Ruth Bell (LE132P)
Jim McCormick (PM222A)
Debra Dobkowski (TS-788)
Terrell Hunt (LE132A)
Stan Abramson (LE132A)
Ken Shiroishi (EN-342)
John J. Neylan III "
Phyllis Flaherty "
John Martin "
Ralph Turpin "
Dr. Dexter Goldman "

Dr. John Mackenzie
Western Compliance Representative, OCM
Region IX

Louis Gitto, Director
Air Managment Division, Region I

Barbara Metzger, Director
Environmental Services Division, Region II

Stephen R. Wassersug, Director
Hazardous Waste Management Division, Region III

Winston Smith, Director
Air Division, Region IV

William H. Sanders III, Director
Environmental Services Division, Region V

Allyn Davis, Director
Air and Waste Management Division, Region VI

Art Spatlin, Director
Air and Waste Management Division, Region VII

Irv Dickstein, Director
Air and Toxic Substances Division, Region VIII

Harry Seraydarian, Director
Toxics and Waste Management Division, Region IX

Gary O'Neal, Director
Air and Toxics Division, Region X

TSCA Good Laboratory Practice Regulations

Enforcement Response Policy

TSCA Good Laboratory Practice Regulations

Enforcement Response Policy

OVERVIEW

On November 29, 1983, the Environmental Protection Agency (EPA) published final rules (48 FR 53922, 40 CFR Part 792) establishing Good Laboratory Practice (GLP) standards for the conduct of laboratory studies that are used to obtain data for hazard evaluations under Section 4 of the Toxic Substances Control Act (TSCA). The TSCA GLP regulations became effective on December 29, 1983. They were the result of investigations by the Food and Drug Administration (FDA) and EPA which showed that some studies submitted in support of the safety of regulated chemical substances had not been conducted in accordance with acceptable practice, and that, accordingly, the quality and integrity of such studies were not always adequate. In conjunction with EPA's data audit efforts, the regulations are intended to ensure the high quality of laboratory test data required to evaluate the health and environmental effects of chemical substances regulated under TSCA.

APPLICABILITY

The TSCA GLP regulations apply to any study conducted, initiated, or supported on or after December 29, 1983 that relate to health effects, environmental effects, and chemical fate testing required by TSCA Section 4 test rules. In addition, it is the Agency's policy to expect adherence to the GLP regulations by persons sponsoring or conducting studies under TSCA Section 5 and negotiated testing agreements.

LEVELS OF ACTION

The most commonly used responses to violations of the TSCA GLP regulations that were committed in connection with Section 4 test rules will be notices of noncompliance and civil administrative penalties. Notices of noncompliance generally will involve minor or technical violations that do not, either separately or collectively, have an impact upon the Agency's ability to evaluate chemical substances or mixtures. EPA will seek civil administrative penalties for most other violations. At the other extreme, criminal sanctions are reserved for the most serious violations which reflect a general intent to undermine regulatory requirements.

If studies submitted under negotiated testing agreements and Section 5 of TSCA are not conducted in accordance with GLP requirements, the Agency may elect to consider the data insufficient

to evaluate the health effects, environmental effects, and fate of the chemical. Noncompliance with GLP requirements may also give rise to the issuance of a notice of noncompliance. Civil penalties, however, may only be sought in response to violations committed under Section 4 test rules.

Notice of Noncompliance

All notices of noncompliance (NON) will involve minor, technical, or form violations of the GLP regulations which are not considered substantive. For example, an NON may be appropriate where a laboratory meets all of its testing obligations with only an occasional inadvertent failure to make required periodic observations, and such failure did not affect the reliability and accuracy of the test data. Multiple nonsubstantive violations within a specific GLP regulation citation for a single study (i.e., §792.81(b) or §792.130(e)) shall be considered a single violation.

Since laboratories are required to maintain quality assurance units, errors should be kept to a minimum. Therefore, NONs will be issued when the number of nonsubstantive GLP regulation citation violations (not affecting validity) for separate studies does not exceed 2 for studies falling into the Minor Extent category; 4 for studies falling into the Significant Extent category; and 5 for studies falling into the Major Extent category. Nonsubstantive GLP violations exceeding this number will warrant the issuance of a civil penalty.

Generally, however, an NON will not be appropriate for repeat offenses under Section 4 no matter how minor or technical their nature. Repeat offenses will be considered for second inspections of a single study or first inspections of a repeated study. Although these violations do not currently affect EPA's ability to evaluate these chemicals, continued violations may adversely affect accurate testing and assessment ability in the future.

If OCM cannot clearly identify a single entity in violation, the NON will be issued to both the sponsor and the laboratory. Furthermore, the sponsor is to be informed of situations when only the laboratory is cited in an NON or Administrative Civil Penalty.

Civil Penalty

Assessment of a civil penalty will be appropriate in any case where one or more violations, considered together or separately, have any potential to affect the reliability and accuracy of test data. Both the sponsor and the laboratory generally will be cited in civil penalty assessments.

Criminal Sanctions

In some instances the magnitude of a particular violation or the number of repeat offenses will warrant the use of criminal sanctions under Section 16 of TSCA or 18 U.S.C. 2 or 1001. These are the most serious sanctions available for violations of the GLP regulations. Accordingly, criminal sanctions will be sought in situations that reflect the most serious cases of misconduct.

Several factors distinguish criminal cases from administrative or civil actions. First, criminal sanctions will ordinarily be limited to cases in which the violation is accompanied by evidence of "guilty knowledge" or intent on the part of the responsible party. TSCA imposes criminal penalties only for violations of the Act which are committed "knowingly or willfully." For example, criminal prosecution may be appropriate where a sponsor or laboratory management personnel make an informed policy decision to violate the GLP regulations by falsifying material data or intentionally concealing it through omission or selective reporting.

A second factor to consider is the nature and seriousness of the offense. Of significance is the impact, actual or potential, of a given violation on EPA's regulatory functions.

Third, the compliance history of the responsible party is important. Criminal sanctions become more appropriate as incidents of noncompliance increase. While not a prerequisite, a history of noncompliance will often indicate the need for criminal sanctions to achieve effective deterrence.

The Office of Enforcement and Compliance Monitoring has the lead role in investigating alleged criminal misconduct and referring it to the Department of Justice.

Study Invalidation

Finally, under 40 CFR Section 792.17, EPA may determine that data from a study not conducted in accordance with GLP standards are unreliable for purposes of showing that a chemical is not expected to pose an unreasonable risk. If a person submits such data to EPA under a Section 4 test rule, EPA may require the sponsor to perform the test again since the sponsor has not fulfilled its obligations under Section 4. When studies other than those submitted under Section 4 test rules are not conducted in accordance with the GLP regulations, the Agency may deem those studies unreliable and may determine that existing data are insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance.

(3) Failure to complete required testing after making a commitment to conduct testing.

(4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the failure seriously impairs the Agency's ability to evaluate the substance (GLP violations addressed in a separate ERP).

(5) Failure to submit letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required.

(6) Submitting a letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required.

2) Middle Range (Levels 3 and 4) - Violations which impair the Agency's ability to evaluate chemicals in an important but less than critical way. Level 3 and 4 violations include the following categories:

Level 3

(1) Completing a study but submitting it to EPA more than 30 days after the required date without having an EPA written approved modification to the schedule.

(2) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is impaired in an important but less than critical way.

(3) Failure to submit study plans or submitting study plans more than 30 days after the required date taking into consideration any extensions approved in writing by EPA.

(4) Submitting letters of intent to test or submitting a valid request for exemption from testing more than 30 but within 60 days after the letter of intent to test is required.

Level 4

(1) Failure to submit or submitting interim progress reports more than 30 days after the documents are required.

3) Low Range (Levels 5 and 6) - Violations which minimally impair the Agency's ability to evaluate the hazards of a chemical. Level 5 and 6 violations include the following categories:

Level 5

(1) Completing a study and submitting it to EPA more than 15 but within 30 days after the required date but without an EPA written approved modification to the schedule.

(2) Submitting a letter of intent to test or valid request for exemption from testing more than 15 but within 30 days after the letter of intent to test is required.

(3) Submitting study plans, interim progress reports or submitting final reports more than 15 but within 30 days after the required date without an EPA written approved modification to the schedule.

(4) Initiating a study after the date indicated in the approved study plan without an EPA written approved modification to the schedule but the final report is submitted by the required date and accepted by EPA (late initiated studies resulting in late final reports shall be dealt with as late final reports or late study submissions).

(5) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is minimally impaired.

Level 6

(1) Categories 1, 2, and 3 described under Level 5 above if submitted not more than 15 days after the required date.

CONTINUING VIOLATIONS

Under section 16 of TSCA, EPA may assess penalties for each day a violation continues. Per day assessments will apply when the gravity of the violation warrants a higher penalty than can be assessed through a single day penalty assessment.

Continuing violations include the following categories described in the CIRCUMSTANCES subsection of this ERP:

(1) Falsification of data.

(2) Failure to test.

(3) Failure to complete tests after making a commitment to conduct testing.

(4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in a serious impairment or impairment in an important but less than critical way of the Agency's ability to evaluate the substance.

(5) Failure to submit or late submission of letters of intent to test after required date.

(6) Failure to submit valid requests or submission of invalid requests for exemption from testing after the letter of intent to test is required.

The period of violation should apply from the date the violative action begins to the date EPA grants a modification to the standards or schedule. The number of days for the violation shall be calculated based on the number of days a manufacturer manufactures (imports); or when a processor is required to test, the number of days a processor processes a substance during the entire violative period. When a person both processes and manufactures during the violative period, the number of days shall be based on the greater of the two (either processing or manufacture only when the test rule requires manufacturers and processors to test. If the rule requires only the manufacturer to test, then the violative period is based on the days of manufacture. If a single batch is manufactured or processed in more than one day, each batch shall be calculated as one day in violation, except for continuous operations. Two or more batches manufactured or processed in a single day at the same site shall be calculated as one day in violation.

MULTIPLE VIOLATIONS

Multiple violations will apply to situations where a single manufacturer or processor, or consortium commits to perform more than one test required by a TSCA §4 test rule. Each test found with violations shall warrant the assessment of a separate penalty.

Multiple violations include all of the categories described in the CIRCUMSTANCES subsection of this ERP except for certain instances involving failure to submit study plans. A multiple violation situation shall not exist for study plans if they address all required tests under one test rule and are submitted at the same time by one company or consortium.

ADJUSTMENT FACTORS

Once the GBP has been determined, upward and downward adjustments to the penalty amount may be made in consideration of culpability, history of violations, ability to pay, and such other matters as justice may require. EPA will apply these adjustment factors as described in the TSCA Civil Penalty Policy (45 FR 59770, September 10, 1980). Considerations unique to TSCA §4 test rules are discussed below.

1. Voluntary Disclosure

Penalty reductions up to 25% will be applied for voluntary disclosure of violations by manufacturers or processors subject to a TSCA §4 rule. To be eligible, a manufacturer or processor must make the disclosure prior to being notified of a pending inspection and prior to EPA receiving any information relating to the alleged violation. This reduction may be made in calculating the proposed penalty before issuing a civil complaint. The complaint should state the original penalty, the reduced penalty, and the reason for reduction. All other reductions in the GBP should be made after the complaint is issued.

2. Immediate Voluntary Disclosure

In cases where manufacturers or processors subject to a TSCA §4 rule report potential violations to EPA within 30 days of having reason to believe that they may have a violation, additional penalty reductions up to 25% may be applied.

3. Gains from Noncompliance

Noncompliance with a TSCA §4 test rule may enable a person to accrue significant economic gains, since the responsible party may not expend the necessary funds to properly conduct the required testing or to conduct the test at all. Gains may also be realized because EPA does not regulate many substances or mixtures until required testing is submitted and evaluated. Therefore, the penalty policy specifies that violations likely to result in economic gain result in level 1 penalty calculations for each day the chemical is manufactured, processed or imported. The extent category for level 1 violations depends on the type of study, i.e., chronic, subchronic, or acute and is therefore relative to the costs for such tests. In settling cases, the Agency should assure that the final penalty is greater than the economic gain.

Although it might be argued that in most cases the laboratory (and not the sponsor) will have control over a violative condition, the sponsor's role is crucial to eliminating the environment in which violations can occur. The sponsor approves the protocol and certifies test reports submitted under TSCA. A reasonably prudent and responsible person in the sponsor's position will take measures to ensure that the independent laboratory abides by the GLP regulations, especially since the sponsor is required to certify compliance with them. Finally, the sponsor can include a provision in their contract with the laboratory, to maintain significant control over the laboratory's performance.

2. Gains from Noncompliance

Noncompliance with the TSCA GLP regulations may enable a person to accrue significant economic gains, since the responsible party does not expend the substantial funds that are often necessary to conduct required testing properly or at all. Gains may also be realized because EPA does not regulate many substances until required testing is submitted and evaluated. To the extent readily determinable, an estimate of the economic gains realized by the responsible party as a result of noncompliance will be compared to the GBP, subject to TSCA's $25,000 per violation per day limit upon penalties. The final penalty shall be equal to or greater than the economic gain.